1991

No. 91-13

IN THE

Supreme Court of the United States

OCTOBER TERM, 1991

GENETICS INSTITUTE, INC.,
AND CHUGAI PHARMACEUTICAL CO., INC.,
Petitioners,

v.

AMGEN, INC.,
Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF *AMICI CURIAE* OF PROFESSORS ROGER SPERRY, GERALD HOLTON, EVERETT MENDELSOHN AND DOROTHY NELKIN IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*

Amici are teachers and scholars of science, the history of science, and sociology who appear in their own behalf to address matters that intimately affect and threaten to alter the historically uninhibited access to new scientific knowledge and technological innovation that the patent system has always provided to scientists, scholars and the public — an interest that transcends the perspectives of the parties in this case and that might not otherwise be brought to the Court's attention.[1]

Roger Sperry is Board of Trustees Emeritus Professor and formerly Hixon Professor of Psychobiology at the California Institute of Technology. His areas of research, in which he has published widely over the last 40 years, include neurobiology and the growth of nerve connections. In 1981 he was awarded the Nobel Prize in Medicine and Physiology. His other prizes include the National Medal of Science (1989), the Albert Lasker Medical Research Award (1979), and the Lashley Award of the American Philosophical Society (1976). He is a member of the National Academy of Sciences, the Royal Society, and the USSR Academy of Sciences.

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Everett Mendelsohn is Professor of the History of Science at Harvard University. He has been Vice President of the American Association for the Advancement of Science and has been on the editorial board of SCIENCE, its official journal. He has served on the Council of the History of Science Society and been President of the International Council for Science Policy Studies. He is a member of the American Association for the History of Medicine and an Editor of the JOURNAL OF THE HISTORY OF BIOLOGY. He is a member of the Committee for Responsible Genetics and has served on the National Academy of Sciences Committee on Life Sciences and Social Policy. His more than 60 published works include the books HUMAN ASPECTS OF BIOMEDICAL INNOVATION (1971) and THE SOCIAL PRODUCTION OF SCIENTIFIC KNOWLEDGE (1977).

Dorothy Nelkin is a University Professor at New York University, where she teaches in the Department of Sociology and the School of Law. Her scholarship focuses on the public policies concerning science and medicine, most recently research in genetics. She has served on the Board of Directors of the American Association for the Advancement of Science, on the National Academy of Sciences (NAS) Committee on a National Strategy for AIDS, on the NAS Study Committee on Decision-Making in Applying Advances in Biology and Technology to Health, on the Biotechnology Advisory Panel of the Congressional Office of Technology Assessment, and on the U.S. Department of Health and Human Services Working Group on Data Ownership and Access in Biomedical Research. She is the author or co-author of more than 170 published works, including the books SCIENCE AS INTELLECTUAL PROPERTY: WHO CONTROLS SCIENTIFIC RESEARCH? (1984), DANGEROUS DIAGNOSTICS: THE SOCIAL POWER OF BIOLOGICAL INFORMATION (1989), and CONTROVERSY: THE POLITICS OF TECHNICAL DECISIONS (3d rev.ed. 1991).

SUMMARY OF ARGUMENT

Review of decisions of courts of exclusive jurisdiction, such as the patent decisions of the United States Court of Appeals for the Federal Circuit, can never be precipitated by an inter-circuit conflict. As a result, the Supreme Court must remain vigilant for decisions that may conflict with or undermine congressional policy embodied in law. One such policy, enacted pursuant to the constitutional mandate to "promote the Progress of Science and useful Arts," Art. I, § 8, cl. 8, is the requirement that inventors fully disclose their discoveries in exchange for the protection of a patent monopoly. Any alteration of that fundamental policy should not be accomplished by judicial fiat. The Federal Circuit's decision in this case alters the bargain struck by Congress between the public and inventors by allowing the inventors of genetically engineered cell lines to withhold the exact nature of those cells from the public. Established law and policy have heretofore required patent applicants whose inventions involve new or unique biological material to place samples of their cells in public culture depositories. By exempting genetically altered cells from the traditional deposit requirement imposed in related fields of microbiology, and by dictating that genetic engineers' refusals to make deposits be reviewed only on an *ad hoc* basis, the decision below has profoundly transformed the overall scheme of the U.S. patent system and threatens to handicap the dissemination of new knowledge which is the soul of that system.

ARGUMENT

Although an intercircuit conflict has traditionally been an unstated precondition for the grant of certiorari in most patent cases, that condition is no longer possible. With the creation of the Federal Circuit and its exclusive jurisdiction over patent matters, such intercircuit conflicts will never arise, and yet the need for Supreme Court supervision will certainly continue.[2] We understand this Court's willingness to leave most patent matters to the Federal Circuit, but in the absence of intercircuit conflicts to help identify those cases mandating Supreme Court attention, there is perhaps a special need for the presence of *amicus* participation to help flag those unique situations. And this is certainly one of them, for this is not just another patent case.

I. U.S. PATENT POLICY IS PREMISED UPON FULL DISCLOSURE.

Although the substance of the patent in dispute, a life-saving invention, is, on its own, of truly profound importance, the significance of what is at stake here goes well beyond the invention itself. That issue is the disclosure of, and access to, scientific information essential to the scientific and technological

[2] Now that conflicts among the circuits cannot develop on matters of patent law, it is certainly arguable that this Court has a *greater* than normal responsibility to assure itself that the Federal Circuit is not pursuing a misguided course. The literature on the subject reflects a consensus that, due to the absence of potential intercircuit disagreements where specialized courts possess exclusive jurisdiction, it is incumbent upon the Supreme Court to adopt important cases as "vehicles" for achieving resolution of issues that would normally be "percolated" through the various circuits. See S. Estreicher & J. Sexton, REDEFINING THE SUPREME COURT'S ROLE: A THEORY OF MANAGING THE FEDERAL JUDICIAL PROCESS 65 (1986); Baker, *Symposium on Supreme Court Advocacy: A Practical Guide to Certiorari*, 33 CATH. U.L. REV. 611, 620 (1984).

progress that is the goal of our patent system. While some may see a tension between the discovery and dissemination of useful knowledge — the enterprise that unites the noblest mission of science with the enlightenment ideals reflected in the Constitution's First Amendment — and the very notion of "intellectual property" whose legal protection is authorized by the Patent Clause of the Constitution's First Article, we do not believe that such a tension need exist if the Patent Act is properly and consistently applied. For the Act and the constitutional clause upon which it is based are premised upon, and in turn require, the fullest disclosure of inventive knowledge to justify the grant of patent rights. The patent applicant must not only provide all information necessary to enable others to practice his invention, he must also set forth what he believes to be the "best mode" for doing so. *See* 35 U.S.C. § 112. This Court has repeatedly affirmed that "the centerpiece of federal patent policy" is "the ultimate goal of public disclosure and use," *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 109 S.Ct. 971, 980-81 (1989). It is the Federal Circuit's decision here which has needlessly created a tension nowhere to be found in the Patent Act itself.

This Court performs among its most vital functions in a society and an economy committed to the robust and uninhibited pursuit of knowledge when it acts to demand that the *quid pro quo* of disclosure in return for patent exclusivity is honored by those seeking patent protection. The Court then ensures that the patent system's private monopolies on the use or technical applications of new knowledge are not perverted into monopolies over that knowledge itself, and that such monopolies are extended only on terms that fully preserve the access of scientists and the general public to the fruits of scientific discovery.

II. A JUDICIAL BODY IS AN INAPPROPRIATE FORUM IN WHICH TO UNILATERALLY ALTER THAT POLICY.

Whatever one might think of Congress' decision to make even living inventions patentable, neither Congress nor any duly authorized policy-making body has ever allowed the inventors of new life forms to patent their discoveries while withholding from the public the only fully reproducible exemplars of those discoveries, as the Federal Circuit manifestly did here. If the history of science and the history of legal, and especially patent, institutions teach a common lesson, it is that such extraordinary decisions to constrict the reach of human knowledge should be made, if at all, only after the fullest and most democratic debate and deliberation.

For Congress to use its powers under the Patent Clause in so knowledge-constricting a manner would be remarkable. For an appointed executive agency only indirectly accountable to the people to do so would be more remarkable still. For unelected, life-tenured judges to make such a choice in the teeth of contrary law and precedent is downright alarming. It is made no less so by the technical jargon through which the choice was expressed, or by the bizarre premise on which it was justified — a premise about the ease with which the work of genetic engineering may supposedly be reduced to a written recipe and replicated, for purposes of further exploration, without direct public access to the unique living materials themselves.

The fact that the Federal Circuit got its science so badly wrong — and its jurisprudence so thoroughly inverted — may not in itself justify plenary review, but that the Federal Circuit did so is further testament to the enduring truth that decisions made in darkness, and cloistered in isolation, are unlikely to survive the light. Whatever the ultimate ruling on the merits

should be — a matter on which we express no necessary view — what is clear is that few issues could be more deserving of this Court's time and attention.

III. THE FEDERAL CIRCUIT'S DECISION PROFOUNDLY ALTERS THE CONGRESSIONALLY SANCTIONED PLAN FOR U.S. PATENT POLICY.

Predictably, the granting of certiorari will be opposed by the respondent not on the overt basis that it fears the financial consequences of an eventual loss on the merits (or even of interim public perception that such a loss might occur), or on the ground that the Federal Circuit's decision to give genetic engineers a special judge-made exemption from congressional (and even constitutional) disclosure requirements was legally sound, but on the ostensible basis that the Federal Circuit's decision in respondent's favor might somehow be read more narrowly than the petitioners and these *amici* read it.

We trust that this Court will see through the respondent's likely protest that the decision below does not really mean what it appears to say. For, try as one might, it is impossible to ignore: (1) the Federal Circuit's explicit recognition that, as the district court expressly found, no scientist could "ever duplicate exactly" the "best mode cell strain" used by respondent (Appendix to Petition for Certiorari "Cert.Pet.App." at A22); (2) the trial court's finding, accepted by the Federal Circuit, that respondent's withholding of this genetically engineered cell strain, in order to exploit this very irreproducibility, evidenced "deliberate concealment" of the best mode, which the Federal Circuit deemed legally "irrelevant" (Cert.Pet.App. at A23); and (3) the fact that the Federal Circuit reached this conclusion on the novel theory that, unlike *naturally occurring* cells — whose concealment would admittedly

be fatal to a patent application once it was established that mere written disclosures would not make those cells fully reproducible (Cert.Pet.App. at A20-A21) — *genetically engineered* cells should be subject to an *ad hoc* and much less stringent judge-made test pioneered by the court below.

By telling genetic engineers that they may be permitted to retain their best mode cell strains as trade secrets even after being awarded a patent monopoly, the decision below ushers in a new era in which the standard of full disclosure of a patentee's discovery may be watered down, on a case-by-case basis, to a standard requiring disclosure only of an invention which, in the Federal Circuit's own words, " 'could be better, could be worse' " than what the patentee had actually discovered. (Cert.Pet.App. at A20). The decision below thus subjects inventors who wish to improve upon or to design around genetic engineering patents — and indeed subjects our entire storehouse of scientific knowledge — to an unpredictable, *ad hoc*, informational lottery.[3]

Amici take no position on the general question of how "active" federal judges ought to be in creatively and aggressively "reading" legal texts to reflect such judges' own visions of how law and society should be organized. But whatever one's view of that matter, surely one must agree that judicial activism is least appropriate in dealing with scientifically complex or technologically dynamic fields in which society's values have

[3] It is important to note that the "best mode" test of 35 U.S.C. § 112 is a relaxed, rather than a stringent, requirement upon the inventor. It does not require the inventor to disclose a mode better than what she knows, but only the best mode of which she is aware — a properly subjective inquiry. *DeGeorge* v. *Bernier*, 768 F.2d 1318, 1324 (Fed.Cir. 1985). In that sense, the "best mode" requirement is a misnomer because it does not require disclosure of the very best mode that is theoretically possible (which might be discovered by others, or in the future), but only that of which the inventor is presently aware. Surely there can be no lighter and more readily fulfilled burden upon a patent applicant than to reveal only what he or she knows, and surely science and the public deserve no less.

been expressed, for better or for worse, in constitutional or statutory provisions leaving to the Executive Branch the ongoing task of adjusting the governing rules to changing circumstances. This is plainly such an area, for in 35 U.S.C. § 114 Congress has empowered the Patent Office, "[w]hen the invention relates to a composition of matter, . . . [to] require the applicant to furnish specimens or ingredients for the purpose of inspection or experiment." The Patent Office's Manual, in § 608.01(p)(C), if fairly read, covers the best mode cell lines involved in this case when it mandates "the making of a deposit of the microorganism or other biological material in a depository that is readily accessible to the public . . . ." It was only by virtue of its novel distinction between genetically engineered and naturally occurring biological material that the Federal Circuit could avoid candidly conceding that it was effectively nullifying the Executive's regulations with respect to biotechnology and substituting its own rules, in violation of Congress' decision to leave the question of when to require a deposit in executive rather than judicial hands. *See Chevron, U.S.A., Inc.* v. *NRDC, Inc.*, 467 U.S. 837, 865-66 (1984).

The decision to trust executive officials rather than judges to make such choices may reflect no ineluctable logic, but it is a corollary of the system of separated powers through which our Constitution structures our legal universe and seeks to assure the diffusion and decentralization of power that, in the end, represent our best hope for preserving an open society.

CONCLUSION

As scientists, historians of science and sociologists, *amici* can testify to the necessity of preserving free, open and robust communication in the pursuit of scientific knowledge and tech-

nological innovation. The overriding institutional goal of science is "the extension of certified knowledge,"[4] and that goal requires uninhibited access to the research and results of other scientists so that those results can be verified, reproduced, and built upon. The community of common inquiry makes possible the discoveries of the researcher working alone in his lab. Indeed, as the great 19th century natural philosopher John Frederick William Herschel observed, science, properly defined, "is the knowledge of the many."[5] Believing that the widest and fullest possible access to knowledge is essential to scientific progress, and is the central mission of the patent system, *amici* respectfully urge this Court to grant a writ of certiorari in order to review the Federal Circuit's decision, which threatens this principle.

Respectfully submitted,

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ARGUMENT

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II. A JUDICIAL BODY IS AN INAPPROPRIATE FORUM IN WHICH TO UNILATERALLY ALTER THAT POLICY.

Whatever one might think of Congress' decision to make even living inventions patentable, neither Congress nor any duly authorized policy-making body has ever allowed the inventors of new life forms to patent their discoveries while withholding from the public the only fully reproducible exemplars of those discoveries, as the Federal Circuit manifestly did here. If the history of science and the history of legal, and especially patent, institutions teach a common lesson, it is that such extraordinary decisions to constrict the reach of human knowledge should be made, if at all, only after the fullest and most democratic debate and deliberation.

For Congress to use its powers under the Patent Clause in so knowledge-constricting a manner would be remarkable. For an appointed executive agency only indirectly accountable to the people to do so would be more remarkable still. For unelected, life-tenured judges to make such a choice in the teeth of contrary law and precedent is downright alarming. It is made no less so by the technical jargon through which the choice was expressed, or by the bizarre premise on which it was justified — a premise about the ease with which the work of genetic engineering may supposedly be reduced to a written recipe and replicated, for purposes of further exploration, without direct public access to the unique living materials themselves.

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III. THE FEDERAL CIRCUIT'S DECISION PROFOUNDLY ALTERS THE CONGRESSIONALLY SANCTIONED PLAN FOR U.S. PATENT POLICY.

Predictably, the granting of certiorari will be opposed by the respondent not on the overt basis that it fears the financial consequences of an eventual loss on the merits (or even of interim public perception that such a loss might occur), or on the ground that the Federal Circuit's decision to give genetic engineers a special judge-made exemption from congressional (and even constitutional) disclosure requirements was legally sound, but on the ostensible basis that the Federal Circuit's decision in respondent's favor might somehow be read more narrowly than the petitioners and these *amici* read it.

We trust that this Court will see through the respondent's likely protest that the decision below does not really mean what it appears to say. For, try as one might, it is impossible to ignore: (1) the Federal Circuit's explicit recognition that, as the district court expressly found, no scientist could "ever duplicate exactly" the "best mode cell strain" used by respondent (Appendix to Petition for Certiorari "Cert.Pet.App." at A22); (2) the trial court's finding, accepted by the Federal Circuit, that respondent's withholding of this genetically engineered cell strain, in order to exploit this very irreproducibility, evidenced "deliberate concealment" of the best mode, which the Federal Circuit deemed legally "irrelevant" (Cert.Pet.App. at A23); and (3) the fact that the Federal Circuit reached this conclusion on the novel theory that, unlike *naturally occurring* cells — whose concealment would admittedly

be fatal to a patent application once it was established that mere written disclosures would not make those cells fully reproducible (Cert.Pet.App. at A20-A21) — *genetically engineered* cells should be subject to an *ad hoc* and much less stringent judge-made test pioneered by the court below.

By telling genetic engineers that they may be permitted to retain their best mode cell strains as trade secrets even after being awarded a patent monopoly, the decision below ushers in a new era in which the standard of full disclosure of a patentee's discovery may be watered down, on a case-by-case basis, to a standard requiring disclosure only of an invention which, in the Federal Circuit's own words, " 'could be better, could be worse' " than what the patentee had actually discovered. (Cert.Pet.App. at A20). The decision below thus subjects inventors who wish to improve upon or to design around genetic engineering patents — and indeed subjects our entire storehouse of scientific knowledge — to an unpredictable, *ad hoc*, informational lottery.[3]

Amici take no position on the general question of how "active" federal judges ought to be in creatively and aggressively "reading" legal texts to reflect such judges' own visions of how law and society should be organized. But whatever one's view of that matter, surely one must agree that judicial activism is least appropriate in dealing with scientifically complex or technologically dynamic fields in which society's values have

[3] It is important to note that the "best mode" test of 35 U.S.C. § 112 is a relaxed, rather than a stringent, requirement upon the inventor. It does not require the inventor to disclose a mode better than what she knows, but only the best mode of which she is aware — a properly subjective inquiry. *DeGeorge* v. *Bernier*, 768 F.2d 1318, 1324 (Fed.Cir. 1985). In that sense, the "best mode" requirement is a misnomer because it does not require disclosure of the very best mode that is theoretically possible (which might be discovered by others, or in the future), but only that of which the inventor is presently aware. Surely there can be no lighter and more readily fulfilled burden upon a patent applicant than to reveal only what he or she knows, and surely science and the public deserve no less.

been expressed, for better or for worse, in constitutional or statutory provisions leaving to the Executive Branch the ongoing task of adjusting the governing rules to changing circumstances. This is plainly such an area, for in 35 U.S.C. § 114 Congress has empowered the Patent Office, "[w]hen the invention relates to a composition of matter, . . . [to] require the applicant to furnish specimens or ingredients for the purpose of inspection or experiment." The Patent Office's Manual, in § 608.01(p)(C), if fairly read, covers the best mode cell lines involved in this case when it mandates "the making of a deposit of the microorganism or other biological material in a depository that is readily accessible to the public . . . ." It was only by virtue of its novel distinction between genetically engineered and naturally occurring biological material that the Federal Circuit could avoid candidly conceding that it was effectively nullifying the Executive's regulations with respect to biotechnology and substituting its own rules, in violation of Congress' decision to leave the question of when to require a deposit in executive rather than judicial hands. *See Chevron, U.S.A., Inc.* v. *NRDC, Inc.*, 467 U.S. 837, 865-66 (1984).

The decision to trust executive officials rather than judges to make such choices may reflect no ineluctable logic, but it is a corollary of the system of separated powers through which our Constitution structures our legal universe and seeks to assure the diffusion and decentralization of power that, in the end, represent our best hope for preserving an open society.

CONCLUSION

As scientists, historians of science and sociologists, *amici* can testify to the necessity of preserving free, open and robust communication in the pursuit of scientific knowledge and tech-